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EXAMINER

PRATS, FRANCISCO CHANDLER

| ART UNIT | PAPER NUMBER |
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1651

DATE MAILED: 10/02/2002 4/

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/720,041

Applicant(s)

SCHLOTHAUER ET AL.

Examiner

Francisco C Prats

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-62 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

The preliminary amendment filed September 26, 2002, has been received and entered.

Note specifically that no part of the preliminary amendments filed April 20, 2001, has been entered. Because of the amendments filed during prosecution of the PCT parent case, neither the claims nor the specification corresponded to the subject matter instructed by applicant to be deleted and/or replaced. The amendments filed April 20, 2001, therefore could not be entered. Applicant should note that the specification presently appears as amended during prosecution of the parent PCT application.

Claims 1-31 have been cancelled.

Claims 32-62 have been added.

Claims 32-62 are pending and are examined on the merits.

Specification

The amendment filed under Article 34 in the PCT parent case, and therefore amendatory to the instant specification, is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention.

The added material which is not supported by the original disclosure is as follows:

During prosecution of the PCT parent application, applicant replaced pages 3-24 as originally filed with pages containing subject matter not part of the disclosure present at the time of filing. See International Preliminary Examination Report (IPER), Form PCT/Separate Sheet/409 (Sheet 1). The specification at the time of filing of the PCT parent case does not provide support for a minimum degree of hydrolysis, or for the specific pH and temperature process conditions recited in the specification as amended.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 32-58, 60 and 61 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably

Art Unit: 1651

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As discussed above with respect to the specification, during prosecution of the PCT parent application, applicant replaced pages 3-24 as originally filed with pages containing subject matter not part of the disclosure present at the time of filing. See International Preliminary Examination Report (IPER), Form PCT/Separate Sheet/409 (Sheet 1). This amendment included changes to the claims as originally filed. The specification at the time of filing of the PCT parent case does not provide support for a minimum degree of hydrolysis, or for the specific pH and temperature process conditions recited in the claims as amended.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32-58, 60 and 61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation "to avoid substantial denaturation peptides" in claim 32 is indefinite. It is not clear whether the term "avoid" excludes all processes which contains denaturation, or whether some degree of denaturation is acceptable, since only avoidance is required, and not absolute exclusion. Also, because of the subjective nature of the term, it is not clear how much denaturation is encompassed by the term "substantial", since the an amount of denaturation considered substantial by one practitioner might not be considered substantial by another. The term "substantially white" in claim 55 is indefinite for the same reasons.

In claim 46, the recitation "said lactose content" lacks antecedent basis in the claims. Claim 46 depends from claim 32, which does not recite anything about "lactose content." It appears that claim 46 should depend from claim 45.

Claim 49 is indefinite in its recitation "-galactosidase". It appears a beta symbol should precede the enzyme name.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

Art Unit: 1651

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 32, 39, 45, 50 and 51 are rejected under 35

U.S.C. 102(b) as being anticipated by Mellqvist et al (U.S. Pat. 4,847,096).

Mellqvist discloses a process of improving the taste and storage stability of whey proteins, whereby a whey protein concentrate is contacted with a protease at 50°C and pH 8 to a degree of hydrolysis of 2.2, after which the enzyme is inactivated by decreasing pH to 4 for 60 min. See column 3, lines 35-45. A holding of anticipation over the cited claims is therefore required.

Claims 59 and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by Chemical Abstracts 114:82552 (Komura et al).

Komura discloses the peptide Leu-His-Leu-Pro-Leu-Pro and its use in treating hypertension. Komura therefore anticipates claims 59 and 62.

Art Unit: 1651

Claim 59 is rejected under 35 U.S.C. 102(b) as being anticipated by Strachan (U.S. Pat. 3,843,621).

Strachan discloses the dipeptide valyl-phenylalanine, thereby anticipating claim 59.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 32-40, 42-44 and 46-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mellqvist et al (U.S. Pat. 4,847,096).

Art Unit: 1651

Mellqvist discloses a process of improving the taste and storage stability of whey proteins, whereby a whey protein concentrate is contacted with the claimed protease Neutrase ® at 20°C and pH 7 to a degree of hydrolysis of 1.2, after which the enzyme is inactivated by decreasing pH to 4 for 60 min. See Example 2, at column 4, lines 20-37. Example 2 of Mellqvist differs from the claims in that Mellqvist uses a temperature which is slightly lower than that claimed.

However, Mellqvist clearly discloses that temperature may be routinely varied as long as the desired degree of hydrolysis is obtained. See column 2, lines 48-55. Moreover, Mellqvist discloses generally that a degree of hydrolysis between 0.5 and 4.0 is desirable in such processes. See column 2, lines 5-12. Thus, the artisan of ordinary skill at the time of applicant's invention clearly would have been motivated to have determined process conditions suitable for performing Mellqvist's process, and would have been motivated to have performed Mellqvist's process under those process conditions, so as to produce a whey hydrolysate with a degree of hydrolysis of 4, as disclosed by Mellqvist as being desirable.

Moreover, the selection of a sweet whey starting material would have been obvious in view of Mellqvist's disclosure that virtually any whey product can be used as a starting material.

Art Unit: 1651

See column 3, lines 23-31. Further still, the use of heat deactivation in Mellqvist's process, and the determination of suitable temperatures therefor, would have been obvious in view of Mellqvist's disclosure of the suitability thereof. See column 3, lines 1-6. Still further, the use of immobilized enzymes is well known in the art, and would have been obvious in view of Mellqvist's disclosure. Further still, the use of a whey substrate containing high amounts of lactose would also have been obvious, in view of Mellqvist's disclosure that virtually any whey product can be used as a starting material. See column 3, lines 23-31. A holding of obviousness over the cited claims is therefore required.

Claims 32 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mellqvist et al (U.S. Pat. 4,847,096) in view of Shimamura et al (EP 0 799 577).

As discussed above, Mellqvist discloses and renders obvious the process recited in claim 32. Mellqvist differs from the claims in that Mellqvist does not disclose the use of ultrafiltration in the enzyme deactivation step. However, Shimamura discloses that protease inactivation by ultrafiltration is convention in processes of preparation enzymatic whey hydrolysates. See page 15, second full

Art Unit: 1651

paragraph. Thus, the artisan of ordinary skill, recognizing from Shimamura the suitability of ultrafiltration as an enzyme-removing step in the preparation of enzymatic hydrolysates of whey, clearly would have been motivated to have used ultrafiltration in Mellqvist's process with a reasonable expectation that it would have functioned at least equivalently to the enzyme inactivation techniques disclosed by Mellqvist. Claim 41 must therefore be considered obvious over the cited references.

Claims 32, 45 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mellqvist et al (U.S. Pat. 4,847,096) in view of Soehnlén (U.S. Pat. 4,358,464).

As discussed above, Mellqvist discloses and renders obvious the process recited in claim 32. Mellqvist differs from the claims in that Mellqvist does not disclose the use of β -galactosidase in treating the whey product, as recited in claims 45 and 49. However, Soehnlén discloses that the use of β -galactosidase in treating a whey product, improves the taste of the product. See abstract. Thus, the artisan of ordinary skill, recognizing from Soehnlén the advantage of β -galactosidase as a taste improving step in the preparation of enzymatic hydrolysates of whey, clearly would have been

Art Unit: 1651

motivated to have used β -galactosidase in Mellqvist's process to further improve the taste of the resulting product. Claim 49 must therefore be considered obvious over the cited references.

Claims 32, 51 and 59-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mellqvist et al (U.S. Pat. 4,847,096) in view of Mullally (Int. Dairy Journal 7:299-303 (1997)). As discussed above, Mellqvist discloses and renders obvious the process recited in claim 32. Mellqvist differs from the claims in that Mellqvist does not disclose the use of the enzymatic hydrolysate produced therein in the treatment of hypertension, as recited in claims 59-62. However, Mullally clearly discloses that hydrolysates of whey produced by proteases having a variety of specificities all possess anti-hypertensive activity. See page 301, Table 1. Thus, in view of Mullally, the artisan of ordinary skill would have reasonably expected the enzymatic whey digests of Mellqvist to have had anti-hypertensive properties as well, and would have been motivated to have used Mellqvist's enzymatic whey digests in a treatment of hypertension. A holding of obviousness is therefore required.

Claim Rejections - 35 USC § 102/103

Claims 51-59 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Mellqvist et al (U.S. Pat. 4,847,096).

The reference discloses a product which appears to be identical to the presently claimed product, based on the fact that the prior art product is produced by contacting the same enzyme, Neutrase®, with the same substrate, whey, to yield a product having the same degree of hydrolysis as recited in the claims. See Example 2, at column 4, lines 20-37. Consequently, the claimed product, including the peptide sequences, appears to be anticipated by the reference.

However, even if the reference product and the claimed product are not one and the same and there is, in fact, no anticipation, the reference product would, nevertheless, have rendered the claimed strain obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact any difference between the claimed product and the prior art product would be the nominal difference expected, due to variations in starting materials and in differing batches of enzymes and starting materials. Thus the claimed invention as a

Art Unit: 1651

whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

With respect to the propriety of this type of alternative rejection, note that MPEP § 2113 states that:

. . . [w]hen the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith. *In re Brown*, 59 CCPA 1063, 173 USPQ 685 (1972).

MPEP § 2113 also clearly states that

'The Patent Office bears a lesser burden of proof in making out a case of *prima facie* obviousness for product-by-process claims because of their peculiar nature' than when a product is claimed in the conventional fashion. *In re Fessmann*, 180 USPQ 324 (CCPA 1974)."

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 703-308-3665. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

Application/Control Number: 09/720,041
Art Unit: 1651

Page 14

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Francisco C Prats
Primary Examiner
Art Unit 1651

FCP
September 30, 2002